

**Amendments to the Specification:**

**Please replace the paragraph on page 1 before the first line as inserted by the Preliminary Amendment filed with the application with the following paragraph:**

-- This application is a divisional of U.S. Application Serial No. 08/466,662, filed June 6, 1995, now issued as U.S. Patent No. 6,130,059, which is a divisional of U.S. Application Serial No. 08/256,848, filed October 21, 1994, now abandoned, which is a U.S. national phase application of PCT/EP93/00472, filed March 2, 1993, and PCT/EP93/00158, filed January 25, 1993. The instant application also claims the benefit of priority of Italian Application Serial No. FI 92 A 000052, filed March 2, 1992. PCT/EP93/00472 was published in English and PCT/EP93/00158 was abandoned prior to publication. The entire contents of each application is hereby incorporated by reference.--

**Please amend the paragraph bridging pages 39, line 18 to page 40, line 9 as follows:**

-- Preferred adjuvants to enhance effectiveness of the composition include, but are not limited to: (1) aluminum salts (alum), such as aluminum hydroxide, aluminum phosphate, aluminum sulfate, etc.; (2) oil-in-water emulsion formulations (with or without other specific immunostimulating agents such as muramyl peptides (see below) or bacterial cell wall components), such as for example (a) MF59 (PCT Publ. No. WO 90/14837), containing 5% Squalene<sup>®</sup>, 0.5% Tween 80<sup>®</sup>, and 0.5% Span 85<sup>®</sup> (optionally containing various amounts of MTP-PE (see below), although not required) formulated into submicron particles using a microfluidizer such as Model 110Y microfluidizer (Microfluidics, Newton, MA), (b) SAF, containing 10% Squalane, 0.4% Tween 80<sup>®</sup>, 5% pluronic-blocked polymer L121, and thr-MDP (see below) either microfluidized into a submicron emulsion or vortexed to generate a

larger particle size emulsion, and (c) Ribi<sup>TM</sup> adjuvant system (RAS), (Ribi Immunochem, Hamilton, MT) containing 2% Squalene<sup>®</sup>, 0.2% Tween 80<sup>®</sup>, and one or more bacterial cell wall components from the group consisting of monophosphorylipid A (MPL), trehalose dimycolate (TDM), and cell wall skeleton (CWS), preferably MPL + CWS (Detox<sup>TM</sup>); (3) saponin adjuvants, such as Stimulon<sup>TM</sup> (Cambridge Bioscience, Worcester, MA) may be used or particles generated therefrom such as ISCOMs (immunostimulating complexes); (4) Complete Freund's Adjuvant (CFA) and Incomplete Freund's Adjuvant (IFA); (5) cytokines, such as interleukins (IL-1, IL-2, etc.), macrophage colony stimulating factor (M-CSF), tumor necrosis factor (TNF), etc.; and (6) other substances that act as immunostimulating agents to enhance the effectiveness of the composition. Alum and MF59 are preferred.--

**Please amend the specification on page 61, lines 2-19, as follows:**

-- The following materials were deposited on December 15, 1992 and January 22, 1993 by Biocine Sclavo, S.p.A., [the assignee of the present invention,] with the American Type Culture Collection, [12301 Parklawn Drive, Rockville, Maryland, phone (301) 231-5519] 10801 University Boulevard, Manassas, VA 20110-2209, under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for Purposes of Patent Procedure.

For the cytotoxin protein (CT):

ATCC No. 69157 *E. coli* TG1 containing the plasmid TOXHH1

ATCC No. n/a *E. coli* TG1 containing the plasmid TOXEE1

For the CAI protein:

ATCC No. 69158 *E. coli* TG1 containing the plasmid 57/D

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**PATENT**

ATCC No. 69159 *E. coli* TG1 containing the plasmid 64/4

ATCC No. 69160 *E. coli* TG1 containing the plasmid P1-24

ATCC No. 69161 *E. coli* TG1 containing the plasmid B/1

For the heat shock protein (hsp):

ATCC No. 69155 *E. coli* TG1 containing the plasmid pHp60G2

ATCC No. 69156 *E. coli* TG1 containing the plasmid pHp605.--